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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/710,430 11/09/00 HANADA

S 11151/5

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IM52/0627

EXAMINER

WILKINS III, H

ART UNIT

PAPER NUMBER

1742

DATE MAILED:

06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

<b>Office Action Summary</b>	Application No. 09/710,430	Applicant(s) HANADA ET AL.	
	Examiner Harry D Wilkins, III	Art Unit 1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 20) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: on page 1, line 4, "to" should be inserted between "relates" and "shape"; on page 2, line 17 "having" should be deleted and "have" should be inserted after "can".

Appropriate correction is required.

### ***Claim Objections***

2. Claims 11 and 12 objected to because of the following informalities: "born" should be "bone" as supported by the specification at least at page 8, in the first full paragraph. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "superelasticity" is not defined by the specification and one of ordinary skill in the art would not be apprised of the scope of the invention. The term "superelasticity" is not defined as to how elastic the alloy must be in order to be "superelastic".

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7, 9-11 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Araya et al (JP 10-219375 A).

Araya et al anticipate the claimed alloy. Araya et al teach (see English abstract) that the alloy is composed of titanium, with niobium and tantalum and optionally tin. The alloy contains 20-60 wt% of niobium plus tantalum and less than 5 wt% tin. Araya et al teach (see English abstract) that it is desirable for the alloy to contain at least 15 wt% niobium and at least 6 wt% tantalum. Araya et al provide (see Table 1) specific examples of the alloy which contain 29 wt% niobium, 13 wt% tantalum and 4.6 wt% tin with the balance titanium. This alloy is equivalent to 20.3 at% niobium, 4.67 at% tantalum, 2.52 at% tin and 72.5 at% titanium. If the extreme lower limits of niobium and tantalum are used, along with the extreme upper limit of tin, the alloy would be 9.06 at% niobium, 1.86 at% tantalum, 2.36 at% tin and 86.72 at% titanium.

Regarding claim 2, Araya et al teach that the alloy may contain 86.72 at% titanium.

Regarding claim 3, Araya et al teach, based on the extreme limits, that the alloy may contain a total of 10.92 at% niobium plus tantalum.

Regarding claim 4, Araya et al teach that the alloy may contain 2.52 at% or 2.36 at% tin.

Regarding claims 5-7, with respect to the properties that the alloy has shape memory characteristics, has superelasticity, and has superelasticity at the human body

temperature, the alloy composition taught by Araya et al overlaps the alloy composition recited in the claims, therefore, one of ordinary skill in the art would have expected that the products taught by the reference would inherently have the same shape memory characteristics and superelasticity as claimed.

Regarding claim 9, Araya et al teach (see English abstract) that the alloy composition is useful as a dental root. Thus, the alloy would have inherently been used as an artificial dental implant.

Regarding claims 10 and 16, Araya et al teach (see English abstract) that the alloy composition is useful as an artificial joint. An arthrosis, as defined by Merriam Webster's Collegiate Dictionary, 10<sup>th</sup> Edition, is an articulation between bones. The same defines articulation as a joint or juncture between bones or cartilages in the skeleton. Thus, an artificial arthrosis is another way of saying artificial joint.

Regarding claim 11, Araya et al teach (see English abstract) that the alloy is useful as a substitutive material for bone.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claim 1 above, and further in view of Farzon-Nia et al (US 5,429,504).

As cited above, Araya et al do not teach that the alloy may be used to make orthodontic appliances.

Farzin-Nia et al teach (see col 2, lines 19-33) orthodontic applications for a titanium-base material which may contain tin and niobium.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make orthodontic appliances as taught by Farzin-Nia et al because the alloy of Araya et al is bio-compatible.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claim 1 above, and further in view of Beyar et al (US 6,127,597).

As cited above, Araya et al do not teach that the alloy may be used to make bone fixators.

Beyar et al teach (see col 3, lines 16-25) that bone fixators have been known to be made of titanium or nitinol (a shape memory alloy).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make a bone fixator as taught by Beyar et al because the alloy of Araya et al is bio-compatible and has high strength.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claim 1 above, and further in view of Regan (US 4,795,458).

As cited above, Araya et al do not teach that the alloy may be used to make thrombus inhibitors (i.e.-stents).

Regan teaches (see col 1 ,lines 51-53) that stents are well known to be made of nitinol, a shape memory alloy of nickel and titanium.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make stents as taught by Regan because the alloy of Araya et al is bio-compatible and has shape memory characteristics.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claim 1 above, and further in view of Kizelshteyn et al (US 5,215,105).

As cited above, Araya et al do not teach that the alloy may be used to make catheter introducers.

Kizelshteyn et al teach (see col 3, lines 58-64) that it is well known in the art to make catheter introducers from shape memory alloys.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make a catheter introducer as taught by Kizelshteyn et al because the alloy of Araya et al is bio-compatible and has shape memory characteristics.

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claim 1 above, and further in view of Besselink et al (US 5,551,871).

As cited above, Araya et al do not teach that the alloy may be used to make a Harrington bar (i.e.-a device to correct scoliosis).

Besselink et al teach (see col 3, line 58 to col 4, line 22) that shape memory alloys, such as titanium-nickel-niobium, are useful as a scoliosis correction system inside a patient's body where repeated adjustment is often not necessary or desirable but stability is. A standard type of scoliosis correction is the use of a Harrington bar, as evidenced by Applicant's admission (see specification page 7, lines 4-6).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make a Harrington bar as taught by Besselink et al because the alloy of Araya et al is bio-compatible, has shape memory characteristics and has high strength.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Nakanishi et al (JP 58-157934 A) teach Ti-Ni shape memory alloy where Nb, Ta and Sn can be added;
- b. Wang et al (US 4,857,269) teach a titanium-base alloy which can contain Nb, Ta and Sn; and,
- c. Harada et al (US 5,827,231) teach a blood vessel dilator which is made of a titanium-base alloy.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harry D Wilkins, III whose telephone number is 703-305-9927. The examiner can normally be reached on M-F 8:15am-4:45pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V King can be reached on 703-308-1146. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Harry D Wilkins, III  
Examiner  
Art Unit 1742

hdw  
June 25, 2001

  
**ROY KING**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1700**